(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephradine used in making the batch for potency, moisture, pH, cephalexin content, identity, and crystallinity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) The cephradine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) the batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 10.0 micrograms of cephradine per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in §442.40(b)(1)(ii) of this chapter, preparing the sample as follows: Blend a representative number of capsules in a high-speed glass blender jar with sufficient distilled water to give a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to 1 milligrams of cephradine per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

[40 FR 26272, June 23, 1975, as amended at 50 FR 19919, May 13, 1985]

§442.140c Cephradine tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephradine tablets are composed of cephradine and one or more suitable and harmless diluents, binders, lubricants, and colorings. Each tablet contains 1,000 milligrams of cephradine. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephradine that it is represented to contain. Its moisture content is not more than 6.0 percent. It disintegrates within 30 minutes. The cephradine used conforms to the standards prescribed by §442.40(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephradine used in making the batch for potency, moisture, pH, cephalexin content, identity, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The cephradine used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 10.0 micrograms of cephradine per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in §442.40(b)(1)(ii), except prepare the sample and calculate the cephradine content as follows:

(*a*) *Preparation of sample.* Blend a representative number of tablets in a high-speed glass blender jar with sufficient distilled water to give a stock solution of convenient concentration.

Further dilute an aliquot of this solution with distilled water to 1 milligram of cephradine per milliliter (estimated).

(*b*) *Calculations.* Calculate the cephradine content as follows:

$$\text{Milligrams per tablet} = \frac{A_u \times P_a \times d}{A_s \times 1{,}000 \times n}$$

where:

A_u=Absorbance of sample solution;
P_s=Potency of working standard in micrograms per milligram;
d=Dilution factor for sample;
A_s=Absorbance of working standard solution;
n=Number of tablets in the sample assayed.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section.

[45 FR 22919, Apr. 4, 1980, as amended at 50 FR 19919, May 13, 1985]

§ 442.141 Cephradine dihydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephradine dihydrate capsules are composed of cephradine dihydrate and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains 250 milligrams or 500 milligrams of cephradine. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephradine that it is represented to contain. Its moisture content is not more than 11.0 percent. It passes the dissolution test if the quantity *Q* is 85 percent at 60 minutes. The cephradine dihydrate used conforms to the standards prescribed by § 442.41(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephradine dihydrate used in making the batch for potency, moisture, pH, cephalexin content, identity, and crystallinity.

(*b*) The batch for potency, moisture, and dissolution.

(ii) Samples required:

(*a*) The cephradine dihydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 100 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the hydroxylamine colorimetric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute and aliquot of the stock solution with solution 1 to the reference concentration of 10.0 micrograms of cephradine per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in § 442.40(b)(1)(ii), except prepare the sample solution and calculate the cephradine content as follows:

(*a*) *Preparation of sample solution.* Blend a representative number of capsules in a high-speed glass blender jar with sufficient distilled water to obtain a stock solution of convenient concentration. Further dilute an aliquot of this solution with distilled water to a concentration of 1 milligram of cephradine per milliliter (estimated).

(*b*) *Calculations.* Calculate the cephradine content as follows:

$$\text{Milligrams per capsule} = \frac{A_u \times P_a \times d}{A_s \times 1{,}000 \times n}$$

where:

A_u=Absorbance of sample solution;
P_s=Potency of working standard in micrograms per milligram;
d=Dilution factor for sample;
A_s=Absorbance of working standard solution;
n=Number of capsules in the sample assayed.